K120964

MAY 25 2012

510(k) SUMMARY

Upstream Peripheral Technologies GR Catheter

Applicant Information:

Upstream Peripheral Technologies Ltd.
ARAN Building
P.O. Box 3067
43 Haeshel Street
Caesarea 38900
Israel

Phone: (972) 4-6239014
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Contact Person: Dan Rottenberg
Date Prepared: March 30, 2012

Device Information:

Trade Name:	Upstream GR Catheter
Common or Usual Name:	Percutaneous Catheter
Classification:	Class II per 21 CFR 870.1250
Product Code:	DQY
Predicate Device:	Endocross Ltd Enabler-P Support Catheter (K082339)

Intended Use / Indications for Use:

The Upstream GR Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for guidewire exchange.

Technological Characteristics:

The Upstream GR Catheter is a sterile, single-use, dual-lumen catheter, having anchoring balloon and funnel at its distal tip, and Y-connector at its proximal end.

The Upstream GR Catheter is intended for use with up to 0.035" guidewires. The Upstream GR Catheter is provided in 100 cm effective length and its shaft's outer diameter is 1.7mm (5Fr). A hub at the Y-connector center port, at the proximal end of the Upstream GR Catheter, allows guidewire access. The Y-connector side port is used for balloon inflation and deflation. The

distal balloon is used for catheter anchoring and centering. The distal funnel is used as soft tip and soft stopper when an occlusion is reached.

Safety and Performance Data:

The Upstream GR Catheter has been evaluated for biocompatibility in accordance with ISO 10993 to ensure that the materials used in the manufacturing of the device are biocompatible. These tests included:

- cytotoxicity,
- sensitization,
- irritation/intracutaneous reactivity,
- systemic toxicity (acute),
- complement activation,
- hemocompatibility (hemolysis and thromboresistance), and
- pyrogenicity.

Additionally, in vitro bench testing has been performed, based on Upstream's internal requirements and requirement listed in ISO-10555-1, Sterile, single-use intravascular catheters-part-1, and ISO-10555-4, Balloon dilatation catheters, including:

- tensile force testing;
- air leakage testing;
- corrosion resistance testing;
- liquid leakage pressure testing;
- catheter torque testing;
- kink testing;
- tip test;
- freedom from leakage;
- balloon burst testing;
- surface and dimensional analysis;
- radiopacity testing;
- package testing; and
- sterilization validation testing.

All of these tests demonstrated that the Upstream GR Catheter meets its intended performance specifications.

Substantial Equivalence:

The Upstream GR Catheter and the predicate device have the same intended use and indications for use and very similar technological characteristics and principles of operation. The minor technological differences between the Upstream GR Catheter and its predicate device raise no new types of safety or effectiveness questions. In vitro verification testing demonstrates that the Upstream GR Catheter performs as intended and meets all design specifications with respect to

its mechanical and handling characteristics, and that its materials are biocompatible. Thus, the Upstream GR Catheter is substantially equivalent to the Enabler-P Support Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Upstream Peripheral Technologies
c/o Janice M. Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market St., 29th Floor
Philadelphia, PA 19103

MAY 25 2012

Re: K120964
Trade Name: Upstream GR Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 30, 2012
Received: March 30, 2012

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number (if known): K 120964

Device Name: Upstream GR Catheter

Indications for Use:

The Upstream GR Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for guidewire exchange.

Prescription Use _____X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120964

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